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Akebia Announces Publication Highlighting Potential Benefits of HIF Treatments for Patients with Renal Anemia

-- Study Confirms Association Between Higher Altitude and Favorable Changes in Dialysis Patients --

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Akebia Therapeutics, Inc. (NASDAQ:AKBA), a biopharmaceutical company focused on delivering innovative therapies to patients with kidney disease through the biology of hypoxia-inducible factor (HIF), today announced the publication of a study which concluded that higher altitude is associated with higher hemoglobin levels and lower mortality, despite lower utilization of erythropoiesis-stimulating agent (ESA) and intravenous iron. Treatments that mimic the effect of higher altitude, such as HIF therapies, may provide beneficial effects for renal anemia patients, including improved iron mobilization and erythropoietin synthesis. The article, titled "The Effect of Altitude on Erythropoiesis-Stimulating Agent Dose, Hemoglobin Level, and Mortality in Hemodialysis Patients," was published online in the *Journal of Nephrology*.

"This study demonstrates that treatments mimicking the effect of higher altitudes may be beneficial for patients with renal anemia," said Brad Maroni, MD, Chief Medical Officer of Akebia. "We believe that vadadustat may be an effective therapeutic alternative for renal anemia as it exploits the same mechanism of action used by the body to naturally adapt to the lower oxygen levels associated with a moderate increase in altitude. We are currently evaluating vadadustat in our global Phase 3 program for patients with anemia related to chronic kidney disease, and look forward to reporting the results of these trials when they become available."

The study examined data collected during 2012 after changes were implemented to both U.S. ESA product labeling and the reimbursement policy for injectable drugs for dialysis patients, which resulted in marked ESA dose reductions for the treatment of anemia. The study found that residence at higher altitude was associated with improved anemia outcomes compared to those closer to sea level, including higher mean hemoglobin levels and lower mortality despite lower proportion of ESA and intravenous iron use. As a result, treatments that simulate the body's natural response to higher altitude may be beneficial to patients with renal anemia.

The retrospective, observational study of over 99,200 hemodialysis patients was conducted in collaboration with DaVita Clinical Research, a wholly-owned subsidiary of DaVita Inc. The de-identified dataset contained information on patient demographics, disease history, comorbidities, dialysis-specific information for each treatment session, laboratory results, such as hemoglobin and intravenous anemia medications administered at dialysis sessions (ESAs and iron). DaVita uses a single ESA (epoetin alfa), which is delivered intravenously. Patients included in the analysis had received in-center hemodialysis treatment at a DaVita facility, and had been receiving dialysis for six months or more to allow for equilibration of anemia management after dialysis initiation. The full manuscript is available on the *Journal of Nephrology* website at: http://link.springer.com/article/10.1007%2Fs40620-016-0350-1.

About Anemia Related to Chronic Kidney Disease

Approximately 30 million people in the U.S. have chronic kidney disease (CKD), with an estimated 1.8 million of these patients suffering from anemia. Anemia results from the body's inability to coordinate red blood cell production in response to lower oxygen levels due to the progressive loss of kidney function, which occurs in patients with CKD. Left untreated, anemia significantly accelerates patients' overall deterioration of health with increased morbidity and mortality. Renal anemia is currently treated with injectable recombinant erythropoiesis stimulating agents, which are associated with inconsistent hemoglobin responses and well-documented safety risks.

About Akebia Therapeutics

Akebia Therapeutics, Inc. is a biopharmaceutical company headquartered in Cambridge, Massachusetts, focused on delivering innovative therapies to patients with kidney disease through hypoxia-inducible factor biology. Akebia's lead product candidate, vadadustat, is an oral therapy in development for the treatment of anemia related to chronic kidney disease in both non-dialysis and dialysis patients. Akebia has commenced its vadadustat Phase 3 Program, which includes the PRO$_2$TECT studies for non-dialysis patients with anemia secondary to chronic kidney disease and INNO$_2$VATE studies for dialysis-dependent patients. For more information, please visit our website at www.akebia.com.

Forward-Looking Statements

This press release includes forward-looking statements. Such forward-looking statements include those about Akebia's strategy, future plans and prospects, including statements regarding the potential indications and benefits of vadadustat, clinical development plans and potential release of clinical data. The words "anticipate," "appear," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; the ability of Akebia to successfully complete the clinical development of vadadustat; the funding required to develop Akebia's product candidates and operate the company, and the actual expenses associated therewith; the cost of the Phase 3 studies of vadadustat and the availability of financing to cover such costs; the timing and content of decisions made by the FDA and other regulatory authorities; the rate of enrollment in clinical studies of vadadustat; the actual time it takes to initiate and complete clinical studies; the success of competitors in developing product candidates for diseases for which Akebia is currently developing its product candidates; and Akebia's ability to obtain, maintain and enforce patent and other intellectual property protection for vadadustat. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Annual Report on Form 10-Q for the quarter ended June 30, 2016, and other filings that Akebia may make with the Securities and Exchange Commission in the future. Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

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